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CERTIFICATION OF TRANSLATOR

I, Paul Cosmovici, of Acacias, Switzerland, hereby declare that I am fluent in French and English and that, to the best of my knowledge and belief, the following English language translation of WO03/007828 is a true and correct translation of the accompanying French language document

Signed this 16th day of January 2004

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Translation of WO03/007828 as filed

FLEXIBLE VERTEBRAL LINKING DEVICE

FIELD OF THE INVENTION

The invention relates to a posterior flexible vertebral linking device which works in tension, compression and flexion, and which damps all mechanical stresses. This device will have operational advantages that will be described.

PRIOR ART:

We know many posterior vertebral attachment units rigidifying a certain number of vertebrae by depriving them of any mobility, thus allowing the containment of all mechanical stresses. However, the first vertebra adjacent to this rigid block keeps all its mobility and this abrupt discontinuity between the rigid block and this free vertebra very often generates a very high stress of the linking elements. The result is an acceleration of the degeneration of this level.

This problem was only partially solved by semi-rigid systems conceived to create an intermediate rigidity between the mobile vertebrae and the fixed vertebrae. These systems present the following disadvantages:

Either: they work only in tension: this is the case of all the devices based on artificial ligaments. These systems are hardly elastic and leave with the discretion of the operator the care to regulate the tension in particular making thus random the mechanical characteristics in the operating mode tension/compression that concerns us.

Or: they work in compression with a thrust in tension, which makes these devices ineffective once they must assist displacements in extension.

In either case: none of the known devices entirely solves the problem which is posed, namely, damping the mechanical stresses existing in tension/compression and flexion to which a moving vertebra can be subjected

We will name the first prior art: patent EP 0576 379 A1 which presents a
5 shock absorber which seems to approach the most closely at least from the point of view of the general outline of this invention; claim 1 of this patent protects "a uni-axial shock absorber working only in compression while playing the part of an abutment which opposes any displacement of the piston beyond a given value...

In this case the exponential limitation of the displacement solved by the
10 prior art, is a problem which has nothing to do with that the person who wants to solve the present invention.

We now quote a second prior art: the patent application N° 0012998 which describes and claims "a flexible and cast solid vertebral linking device functioning in a multidirectional way". This anteriority does not solve exactly the same
15 problem as the one that the present invention seeks to solve, this invention having different means and functions.

In the present invention, one can choose in a precise way the desired working method: tension/compression or flexion, or the combination of the two working methods, this in order to avoid any contact between the articular facets.

DESCRIPTION

We will list the drawings which help us understand the invention.

Figure 1 and 1 bis of sheet 1/6 presents perspective views (two alternative embodiments) of the device in the case of a working method combined in tension,
5 compression and flexion.

The figures 2 and 2 bis of sheet 1/6 are longitudinal cross-sections of two alternatives of the same device.

Figure 3 of sheet 2/6 is an exploded view of the device and its means.

Figure 4 of sheet 3/6 is a view in perspective of the device working only in
10 tension/compression.

Figure 5 of sheet 3/6 is a cross-section of the device working only in tension/compression.

Figures 6 to 11 of sheet 4/6 represent all the individual parts constituting the device.

15 Figure 12 of sheet 4/6 shows another specific means working according to the tension/compression mode.

Figure 13 of sheet 5/6 shows an alternative of the device working along two axes.

Figures 14 to 17 of sheet 5/6 show four forms of the mobile end of another
20 alternative of device 1.

Figure 18 of sheet 6/6 shows the device in position.

The device 1 consists of two sets of means: A first set of means 11 composed of rigid means manufactured out of preferably metal, biocompatible material ensuring a good mechanical resistance of the device by completely
25 transmitting the forces.

A second set of means 12 formed of flexible or damping means manufactured out of viscoelastic biocompatible materials, supporting the repeated elastic strain. It is the combination of these two sets of means which makes possible the functioning of the invention.

The first set of means 11 includes four mechanical structures 110, 112, 114, 116 which have the function of transmitting the stresses, without becoming deformed, and to which device 1 is subjected.

5 The mechanical structure 110 is made up of a mechanical rod 111, one of its ends being surmounted by a circular plate 113b connected to the aforementioned rod 111 with a broad joining radius 113a, the whole being able to slide in the hollow part of the structure 114 which encloses a visco-elastic element 121.

10 The mechanical structure 112 is a cap provided with a thread 117 allowing for the fixing of the aforementioned structure 112 on structure 114; the means 112 has a shoulder area 118 which makes possible the enclosure of a viscoelastic-centering ring 121 between the plate 113b and itself.

The mechanical structure 114 is made up of two hollow cylinders, one of which is tapped to allow the fixing of a rod 116 with a threaded end. The means 15 110 and 116 will be fixed on the vertebrae to allow the operation of the device 1.

The second set of means 12 is made up of two viscoelastic means 121 and 122.

The first means 121 is preferably a centering ring which lets the rod 111 slide in its center

20 The second means 122 is a disc full of viscoelastic material. These two centering rings 121 and 122 can undergo compressive stresses which may not be uniformly distributed, they were conceived to resist many cyclic fatigue stresses without breaking, tests were carried out in this direction, means 121 and 122 are able to undergone these tests of elastic deformation as many times as necessary.

The selected material is preferably a biocompatible polyurethane; thanks to their integration inside mechanic means 110, 112, 114, 116, the viscoelastic means 121 and 122 are protected by the preceding mechanical structures of the aggressive environment of the human body, which avoids in particular the formation of fibers around these means which could deteriorate the viscoelastic properties of the material and consequently disturb the correct operation of device 1.

This device 1 makes possible the damping of the stresses in tension/compression and flexion which it undergoes by the intermediary of rods 110 and 116. This function is assured owing to the fact that means 112 has a sufficiently broad opening 119 to allow a clearance of rod 111 and that there is a functional allowance between plate 113 and the hollow body of means 114; the shoulder area 118 serves as a stop and maintains in its housing the viscoelastic mass 121 thus locked up.

If one wishes to work in a uni-axial mode of tension/compression, means 112 is replaced by another means 115 equipped with a threading 117, which includes a cap 115c, whose opening 119 is adjusted to the diameter of the rod 110 while being extended by a guiding rod 115a.

This device 1 is thus able to react dynamically to the stresses applied. It is essential that structure 114 comprises a bore 114a to allow a guidance without excessive friction of rod 110 in the aforementioned means 114.

The adjustment of the diameter of the viscoelastic centering rings 121 and 122 must be carried out with precision to enable them to be crushed freely until a stress threshold corresponding to a point of contact of the bore 114a of means 114.

An alternative of the set of means 11 includes metal structures having the same functions as the structures 110, 112, 114, 116, but the assembly of these three parts (110, 130, 131) being of a weaker barrier than that of the structures previously described (fig 2).

- 5 The rod 131 is fixed at its cap 130 by the intermediary of a threading located on shoulder 132 of the rod.

In the case of this alternative, the possibilities of displacement of rod 110 subjected to the stresses in flexion are ensured by play 119 located between cap 130 and rod 110.

- 10 For a uni-axial operation of device 1, it is preferable to use means 110, 112, 114, 116 which provide a better guidance of rod 110. If small overall dimensions are needed, means 110, 130, 131 may be preferably used.

- Device 1 is able to function with rods 110 and 131 moving on convergent axes (fig 13) with a small angle of displacement and according to given clearances.
- 15

The set of means 12 is therefore comprised of two visco-elastic means 141 and 142. The means 141 is a cylinder full of visco-elastic biocompatible material, and whose face in contact with a plate is inclined. The means 142 is a centering ring whose face in contact with the back of a plate is inclined.

- 20 The set of means 11(rigid means) is identical to the previous one that is described above, the orifice 119 being however eccentric depending on the chosen angle. The shape of orifice 119 is defined depending on the clearances which are allowed to the rod 110.

- The rod 110 is thus able, thanks to these new technical characteristics, to function in tension/compression with a given angle with respect to the rod 116 or the rod 131 in case in which the 119 orifice is eccentric and adjusted to the rod 116 or 131 (figure 14).
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The rod 110 forming an angle as against the rod 116 or 131 (the case in which the 119 orifice is oblong and eccentric) can in this case function equally well in tension/compression as in lateral flexion. (Fig. 15).

5 The rod 110 can function in tension/compression and in flexion following a preferred axis which can be for instance in the sagittal plane of the spinal column and this one on the one side and one the other side of a given position of the rod 110 forming at rest an angle with the rod 116 or the rod 131, this also in the case where the means 119 is oblong or eccentric, (figure 16).

10 Finally, the rod 110 can function in tension/compression and in flexion in all directions, forming an angle, as against the rod 116 or 131 in case the orifice 119 is eccentric or larger than the diameter of the rod 110 (figure 17).